REMARKS

Claims 1-4 and 14-16 have been canceled without prejudice to, or disclaimer of, the subject matter contained therein. Applicants maintain that the cancellation of a claim makes no admission as to its patentability and reserve the right to pursue the subject matter of the canceled claims in this or any other patent application.

Correction of Inventorship under 37 CFR §1.48(b)

Applicant requests that several inventors be deleted, as these inventors' inventions are no longer being claimed in the present application as a result of prosecution. The fee as set forth in § 1.17(i) is submitted herewith.

Specification

The Examiner objected to the specification because it contains embedded hyperlinks. Applicants have amended the specification to address the Examiner's concern. In particular, Applicants have replaced the hyperlink with text that describes the location of the website. The amended text no longer constitutes browser executable code.

Claim Objections

The claims were objected to for improper numbering because they contain the letter "c." Applicants have amended the claims to delete the letter "c".

Rejections Under 35 U.S.C. §101

Claims 19-20 were rejected as encompassing non-statutory subject matter because they could read on naturally existing cells. Applicants have amended the claims to recite that the claimed cells are isolated.

Claims 1-20 were rejected on the assertion that they are not supported by a specific asserted utility or a well established utility. The Examiner asserts that the disclosed utility is for "research purposes" where stimulation of TNF-α is desired and for "therapeutic treatment" of conditions in which enhanced TNF-α would be beneficial. The Examiner asserts that the specification does not teach how PRO263 functions and that the specification does not teach any particular condition where it is beneficial to enhance levels of TNF-α. The Examiner further asserts that it is clinically more desirable to block the effects of TNF-α.

As attested in the accompanying Declaration of Paul Godowski, as of October 29, 1997, the filing date of the earliest application to which the present application claims priority, it was known that enhanced TNF-α levels are beneficial in treating certain conditions, such as cancer

and viral infection, and in reducing the deleterious effects of ionizing radiation. As attested in the accompanying Declaration, references published prior to October 29, 1997 described the therapeutic benefits of enhancing TNF-α levels. In addition, while Applicants realize that actions taken by the PTO in other patent applications are not binding on the PTO with respect to the present application, Applicants note that numerous patents issued before October 29, 1997 relate to the therapeutic benefits of enhancing TNF-α levels, indicating that prior to October 29, 1997 the PTO found that inventions relating to the enhancement of TNF-α levels met the requirements of 35 U.S.C. §101.

The present specification describes how to use the claimed polynucleotides to make polypeptides which enhance TNF-α levels. (See Paragraphs [0283]-[0309] and Examples 6-9 of the specification). As attested in the accompanying Declaration, the polypeptides encoded by the claimed polynucleotides can be used to treat the conditions known to be ameliorated by increasing TNF-α levels.

Furthermore, as acknowledged by the Examiner in the Office Action dated September 10, 2004 and attested in the accompanying Declaration, as of October 29, 1997 it was known that there are certain conditions in which it is beneficial to lower the levels of TNF-α. These conditions include rheumatoid arthritis and Crohn's disease. As attested in the accompanying Declaration, references published prior to October 29, 1997 described the therapeutic benefits of decreasing TNF-α levels. In addition, while Applicants realize that actions taken by the PTO in other patent applications are not binding on the PTO with respect to the present application, Applicants note that numerous patents issued before October 29, 1997 relate to the therapeutic benefits of decreasing TNF-α levels, indicating that prior to October 29, 1997 the PTO found that inventions relating to decreasing TNF-α levels met the requirements of 35 U.S.C. §101.

As described in Paragraphs [0361]-[0390] of the specification, the polypeptides generated from the claimed polynucleotides can be utilized to generate antibodies which neutralize the activity of the polypeptide. Pharmaceutical compositions comprising the antibodies can be prepared as described in Paragraphs [0400]-[0409] and Example 10 of the specification. As attested in the accompanying Declaration, such antibodies can be used to reduce the activity of the PRO263 polypeptide, thereby lowering TNF-α levels and achieving a therapeutic benefit.

For the foregoing reasons, Applicants maintain that the claimed polynucleotides satisfy the requirements of 35 U.S.C. §101.

Rejections Under 35 U.S.C. §112, first paragraph

Claims 1-5 and 14-20 were rejected under the first paragraph of 35 U.S.C. §112 on the assertion that they encompass subject matter which was not described in the specification. The Examiner asserts that the claims encompass variants or nucleic acids which hybridize to SEQ ID NO: 5 which have not been described in the specification.

Claims 1-4 and 14-16 have been canceled. Claim 5 has been amended to recite that the claimed polynucleotides stimulate TNF-α release from human blood. Applicants maintain that this amendment provides sufficient distinguishing characteristics of the genus to satisfy the requirements of 35 U.S.C. §112.

Claims 17-20 have been amended to refer to the nucleic acids of Claim 6, which the Examiner acknowledges meet the requirements of 35 U.S.C. §112.

In view of the foregoing, Applicants respectfully request that this rejection be withdrawn.

Rejections Under 35 U.S.C. §112, second paragraph

Claim 14 was asserted to be indefinite for failing to define "stringent conditions." Applicants have canceled Claim 14.

Rejections Under 35 U.S.C. §102

Claims 1-4 and 14-20 were rejected on the assertion that they are anticipated by U.S. Patent No. 5,942,417 filed July 15, 1997 and claiming priority to a provisional application filed July 15, 1996. The Examiner asserts that the cited patent discloses a sequence which is 96.6% identical to SEQ ID NO: 5.

Applicants have canceled Claims 1-4 and 14-16. Claims 17-20 have been amended to refer to the nucleic acids of Claim 6. As the nucleic acids of Claim 6 are not anticipated by the cited reference and were not rejected by the Examiner over this reference, Applicants respectfully maintain that these claims are in condition for allowance.

Conclusion

The present application is believed to be in condition for allowance, and an early action to that effect is respectfully solicited. Applicants invite the Examiner to call the undersigned if any issues may be resolved through a telephonic conversation.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: Dec. 10, 2004

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